

REMARKS

This Amendment is responsive to the Office Action dated March 31, 2006. Applicants have amended claims 1, 5-9, 19, 24, 28, and 33 and canceled claims 3, 12-17, 23 and 26. Claims 1, 2, 4-11, 18-22, 24, 25 and 27-39 are now pending.

In this Amendment, Applicants have amended paragraphs [0040], [0055] and [0059] as suggested by the Examiner. No new matter has been introduced.

With this Amendment, Applicants are submitting a replacement drawing sheet for sheet 5 of the present application. FIG. 5 has been amended to correct a typographical error, and properly label implantable drug delivery catheter 94. No new matter has been added by way of this amendment to FIG. 5.

In the Office Action, the Examiner objected to claim 24 for an informality. This informality has been addressed via amendment, per the Examiner's suggestion.

In the Office Action, the Examiner advanced a provisional double patenting rejection with respect to co-pending U.S. Patent Application Number 10/441,784. Applicants note the provisional status of this rejection. This rejection will be addressed if and when it is formally applied. Applicants do not necessarily acquiesce to the propriety of the provisional double patenting rejection.

In the Office Action, the Examiner rejected claims 1-3, 5-10, 14, 17-18, 24-27, 28-32 and 38-39 under 35 U.S.C. 102(b) as being anticipated by Krakovsky et al. (U.S. Patent No. 5,454,840) ("Krakovsky"); and rejected claims 1-3, 5-12, 14-20 and 22-39 under 35 U.S.C. 102(e) as being anticipated by Whitehurst et al. (U.S. Patent No. 6,901,294) ("Whitehurst '294").

In addition, the Examiner rejected claims 4, 13 and 21 under 35 U.S.C. 103(a) as being unpatentable over Krakovsky or Whitehurst '294 in view of Whitehurst et al. (U.S. Patent No. 6,885,895) ("Whitehurst '895") and Mann et al. (U.S. Patent No. 6,941,171) ("Mann"); rejected claim 11 under 35 U.S.C. 103(a) as being unpatentable over Krakovsky in view of Whitehurst '294; and rejected claims 12, 15-16, 19-23 and 33-37 under 35 U.S.C. 103(a) as being unpatentable over Krakovsky in view of Mann.

Applicants respectfully traverse the rejections to the extent such rejections may be considered applicable to the amended claims. The applied references fail to disclose or suggest

the inventions defined by Applicants' claims, and provide no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

As a preliminary matter, Applicants respectfully note that the Examiner's analysis appears to confuse the Whitehurst '895 reference and the Whitehurst '294 reference. The Whitehurst '895 primarily concerns erectile dysfunction, whereas the Whitehurst '294 reference primarily concerns prostatic hypertrophy. The Examiner's rejections seem to confuse these references. The rejection under 35 U.S.C. 102(e) based on Whitehurst '294, for example, seems to relate to Whitehurst '895. Applicants have attempted to interpret the Examiner's rejections to the extent possible, and to distinguish the claims from all of the applied references. Each of the independent claims is addressed below.

Independent claim 1

Independent claim 1 recites a method of providing medical therapy to a patient. The method comprises delivering one or more therapeutic stimulation pulses to tissue of a prostate gland via an implantable medical device. In addition, claim 1 has been amended to require that the therapeutic stimulation pulses delivered to the tissue of the prostate gland are defined to treat sexual dysfunction by one or more of the following: causing erection, causing ejaculation, preventing ejaculation, preventing premature ejaculation, and causing erection and preventing premature ejaculation. Each of these possibilities for treating sexual dysfunction are also individually required in dependent claims 5-9, respectively.

In the Office Action, claim 1 (and dependent claims 5-9) were rejected under 35 U.S.C. 102 as being anticipated by Krakovsky and Whitehurst '294. As noted, however, the Examiner's citation to Whitehurst '294 in this rejection seems to have actually relied upon Whitehurst '895. Regardless, none of Krakovsky, Whitehurst '294, or Whitehurst '895 discloses or suggests the features of claim 1.

Krakovsky discloses a device and method for impotence correction. According to Krakovsky, stimulation is provided to specific nerves (such as the pelvic splanchnic nerves or the pudendal nerves) to treat conditions of impotence. Krakovsky, for example, teaches that stimulation of the splanchnic nerves can cause erection and that stimulation of the pudendal nerves can cause ejaculation.

Nothing in Krakovsky, however, teaches stimulation of tissue of the prostate gland. On the contrary, rather than stimulate the prostate tissue, Krakovsky teaches nerve stimulation, e.g., of the pelvic splanchnic nerves or the pudendal nerves. For this reason, claim 1 clearly distinguishes Krakovsky.

Likewise, Whitehurst '895 also teaches nerve stimulation techniques, and lacks any suggestion of stimulation of the prostate tissue to treat sexual dysfunction. In Whitehurst '895, like Krakovsky, the stimulation is never delivered to the prostate tissue to cause erection, to cause ejaculation, to prevent ejaculation, to prevent premature ejaculation, or to cause erection and prevent premature ejaculation, as required by claim 1.

The Whitehurst '294 reference appears to describe stimulation to the prostate gland itself, but does not treat sexual dysfunction, nor any of the specific conditions recited in claim 1. Instead, Whitehurst '294 describes prostate stimulation in a manner that treats benign prostatic hyperplasia (HBP). Nothing in Whitehurst '294 teaches stimulation of the prostate tissue to cause erection, to cause ejaculation, to prevent ejaculation, to prevent premature ejaculation, or to cause erection and prevent premature ejaculation, as required by claim 1.

In view of these distinctions, claim 1 and the respective dependent claims clearly recite subject matter that is novel in view of Krakovsky, Whitehurst '895 and Whitehurst '294. Neither Krakovsky nor Whitehurst '895 discloses or suggests prostate tissue stimulation for sexual dysfunction therapy, but rather, teach nerve stimulation for such purposes. The Whitehurst '895 reference may describe stimulation to the prostate gland, but not in a way that treats sexual dysfunction, nor any of the specific conditions recited in claim 1.

Withdrawal of the rejections of independent claim 1 and dependent claims 2, 4-11 and 18 is respectfully solicited.

Independent claims 19, 24, 28 and 33

Independent claims 19, 24, 28 and 33 all concern prostate gland stimulation to change the fiber structure of the prostate gland. Such techniques may, for example, be useful in treating benign prostatic hyperplasia (BPH). Claims 19 and 33 recite methods of prostate gland stimulations, whereas claims 24 and 28 recite implantable medical devices that perform prostate gland stimulation.

Each of these claims 19, 24, 28 and 33 has been amended at this time. More specifically, these claims have been amended to require a training sequence that defines a first pulse train and a second pulse train, wherein the first pulse train and the second pulse train are each delivered over time periods on an order of a week. According to claims 19, 24, 28 and 33, the second pulse train (which lasts on the order of a week) is delivered after the first pulse train (which also lasts on the order of a week). The second pulse train includes more pulses per unit time than the first pulse train.

In this way, the fiber structure of the prostate gland can be changed in a manner that can remedy effects of benign prostatic hyperplasia (BPH). For example, the prostate gland may become more compliant and thereby remedy effects of BPH.

In view of this claim amendment to independent claims 19, 24, 28 and 33, Applicants respectfully request the Examiner's reconsideration of these independent claims, and the respective dependent claims. None of the applied references discloses or suggests prostate stimulation using a training sequence that defines a first pulse train and a second pulse train, wherein the first pulse train and the second pulse train are each delivered over time periods on an order of a week, the second pulse train being delivered after the first pulse train, and wherein the second pulse train includes more pulses per unit time than the first pulse train.

Claims 30 and 38

Claims 30 and 38 have not been amended at this time. Claim 30 recites a system comprising an implantable medical device that delivers stimulation pulses to a prostate gland, and an agent pump that delivers agents to the prostate gland, wherein the implantable medical device and agent pump are programmed to deliver the stimulation pulses and the agents to the prostate gland in a complimentary fashion.

Claim 38 recites an implantable medical device comprising a stimulator to deliver stimulation pulses to a prostate gland, and an agent pump to deliver agents to the prostate gland, wherein the stimulator and agent pump are programmed to deliver the stimulation pulses and the agents to the prostate gland in a complimentary fashion.

In the Office Action, claims 30 and 38 were rejected under 35 U.S.C. 102(b) as being anticipated by Krakovsky. In addition, claims 30 and 38 were also rejected under 35 U.S.C. 102(e) as being anticipated by Whitehurst '294.

Applicants traverse these rejections. Neither Krakovsky nor Whitehurst '294 suggests the delivery of the stimulation pulses to the prostate gland nor the deliver of agents to the prostate gland, much less the delivery of stimulation pulses and agents to the prostrate gland in a complimentary fashion. As noted above, Krakovsky teaches stimulation of nerves rather than stimulation of the prostate gland, as required by Applicants claims. For drug delivery, Krakovsky teaches the delivery of drugs to a patient's penis, not a patient's prostate gland.

Similarly, Whitehurst '294 fails to disclose or suggest the delivery of stimulation pulses and agents to the prostrate gland in a complimentary fashion. In fact, the cited passages of Whitehurst '294 do not discuss any drug delivery, whatsoever.

With regard to drug delivery, it appears that the Examiner's citations to Whitehurst '294 were meant to be citations to Whitehurst '895. However, Whitehurst '895 also lacks any suggestion of the features of claims 30 and 38. Whitehurst '895 teaches the delivery of stimulation and drug therapy to specific nerves (such as the pelvic splanchnic nerves or the pudendal nerves) to treat conditions of impotence, and does not teach stimulation of prostate gland tissue or the delivery of agents to prostate gland tissue, much less the delivery of stimulation pulses and agents to the prostrate gland in a complimentary fashion.

For at least these reasons, the Examiner has failed to establish a prima facie case of anticipation under 35 U.S.C. 102 with respect to Applicants' independent claims 30 and 38. Withdrawal of the rejections of independent claims 30 and 38 and the respective dependent claims is courteously solicited.

CONCLUSION


All claims in this application are in condition for allowance. Applicants respectfully request reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

Date:

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SHUMAKER & SIEFFERT, P.A.
8425 Seasons Parkway, Suite 105
St. Paul, Minnesota 55125
Telephone: 651.735.1100
Facsimile: 651.735.1102

By:



Name: Kelly Patrick Fitzgerald
Reg. No.: 46,326